

## **Remarks**

Applicants have carefully reviewed the Final Office Action mailed on October 19, 2009 and the Advisory Action mailed January 11, 2010. Applicants respectfully traverse (and do not concede) all objections, rejections, adverse statements, and adverse assertions made by the Examiner. With this amendment and request for continued examination, claims 17, 47, 57, 61, and 63 are amended. No new matter is added. Claims 17, 19, 39, 40, 42-58, 60, 61, and 63 are presented for examination.

## **Claim Rejections Under 35 U.S.C. §103**

Claims 17, 19, 39, 40, 42-56, 61, and 63 are rejected under 35 U.S.C. §103(a) as being unpatentable over Vardi et al. in U.S. Patent No. 6,325,826 in view of Marotta et al. in U.S. Patent No. 6,261,305 and Crocker et al. in U.S. Patent No. 5,843,116. Applicants respectfully traverse the rejection.

The Office Action indicated that Vardi a number of features of the claimed invention but fails that “Vardi fails to disclose ... a bulge portion for expanding the bifurcated stent.” However, the Office Action went on to indicate that Marotta et al. “teaches a bulge portion” and that “substitution of one known element (a single catheter having a single balloon with a body region and a bulge region) for another (two balloon catheters as shown in Vardi) would have been obvious”. We respectfully disagree that the cited art renders the claimed invention obvious.

Regarding claims 17, 19, 39, 40, and 42-46, claim 17 is amended to recite:

17. (Currently Amended) A system comprising:  
only a single catheter, the single catheter having only a single balloon, the single catheter being adapted for insertion into a body vessel and advancement to a vessel bifurcation site, wherein the single balloon includes an elongate body region and a pre-formed ~~predetermined~~ bulge region that protrudes ~~configured to protrude~~ radially outward from the body region when expanded, the pre-formed ~~predetermined~~ bulge region is positioned at a location between a proximal end and a distal end of the body region and at a predetermined location around a circumference of the body region that extends less than the entire circumference of the body region, wherein the pre-formed ~~predetermined~~ bulge region is configured to have different pressure and/or inflation characteristics than the elongate body region; and  
a bifurcation stent including a stent body having a substantially tubular stent wall defining a circumferential plane, and a plurality of

movable members engaged to the stent wall, each of the moveable members being moveable independent of the other moveable members, the stent body being expandable from an unexpanded condition to an expanded condition by expansion of the single balloon extending within the stent wall from at least a proximal end to at least a distal end of the stent body, in the unexpanded condition the plurality of movable members being retained substantially within the circumferential plane of the stent wall and aligned with the pre-formed predetermined bulge region of the single balloon, and in the expanded condition a portion of the plurality of movable members being extended radially outward from the stent wall by the expansion of the predetermined bulge region of the single balloon to form a scaffold, the scaffold defining a side opening in the stent wall; wherein the pre-formed bulge region is configured to protrude radially outward from the body region independently of whether or not the bifurcated stent is disposed on the single balloon.

Applicants respectfully submit that the cited art does not appear to teach or suggest all the limitations of amended claim 17. For example, Marotta et al. discloses a balloon 55 that appears to exert a radially outward force sufficient to urge a leaf portion 120 of an endoprosthesis 100 in a manner that results in the blocking of an opening 35 of an aneurysm 30. Because the leaf portion 120 is formed as a cut-out in the endoprosthesis 100, the balloon 55 appears to “bulge” and, thus, urge the leaf portion 120 in the desired manner. However, the ability of the balloon 55 in Marotta et al. to urge the leaf portion 120 appears to be the result of the shape and configuration of the leaf portion 120 itself and not due to pre-formed structural feature of the balloon 55. In other words, the only reason that the balloon 55 appears to “bulge” is because of the fact that the endoprosthesis 100 is disposed on the balloon 55. Accordingly, the “bulge” is not due to a particular pre-formed structural feature of the balloon 55 but rather is due to the fact that the leaf portion 120 provide less restriction on the balloon 55 (than the remainder of the endoprosthesis) so that the balloon 55 can actually expand to a greater extent adjacent the leaf portion 120.

Therefore, the so-called “bulge” in the balloon 55 is not a pre-formed structural feature of the balloon 55. Instead, the “bulge” is merely the result of the positioning the endoprosthesis 100 on the balloon 55.

Furthermore, the so-called “bulge” in the balloon 55 is not configured to protrude radially outward from the balloon 55 independently of whether or not the endoprosthesis 100 is disposed

on the balloon 55. Instead, in order for the balloon 55 to “bulge”, the endoprosthesis 100 needs to be positioned on the balloon.

Based on at least these distinctions, Applicants respectfully submit that Vardi and Marotta et al., either alone or in combination, fail to teach or suggest all the limitations of amended claim 17. Crocker et al. fails to overcome the shortcomings of the cited art. Accordingly, Applicants respectfully submit that amended claim 17 is patentable over Vardi, Marotta et al., and Crocker et al., to the extent that such a combination is even possible. Because claims 19, 39, 40, and 42-46 depend from claim 17, they are also patentable for the same reasons as claim 17 and because they add significant elements to distinguish them further from the art.

Regarding claims 47-56, claim 47 is similarly amended to recite a pre-formed bulge portion. For reasons similar to those set forth above in relation to claim 17, Applicants respectfully submit that amended claim 47, as well as claims 48-56 depending therefrom, are patentable over the cited art.

Regarding claim 61, this claim is similarly amended to recite a pre-formed bulge region. For reasons similar to those set forth above in relation to claims 17 and 47, Applicants respectfully submit that amended claim 61 is patentable over the cited art.

Regarding claim 63, this claim is similarly amended to recite a pre-formed bulge region. For reasons similar to those set forth above in relation to claims 17, 47, and 61, Applicants respectfully submit that amended claim 63 is patentable over the cited art.

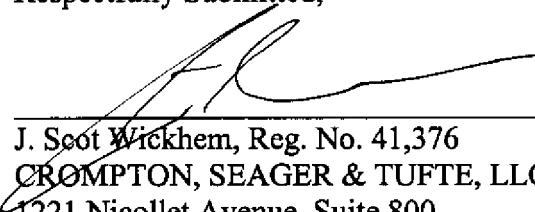
Claims 57, 58, and 60 are rejected under 35 U.S.C. §103(a) as being unpatentable over Vardi et al. in view of Marotta et al. Claim 57 is similarly amended to recite a pre-formed bulge portion. For reasons similar to those set forth above in relation to claims 17, 47, 61, and 63, Applicants respectfully submit that amended claim 57, as well as claims 58 and 60 depending therefrom, are patentable over the cited art.

### **Conclusion**

Further examination and withdrawal of the rejections is respectfully requested. It is respectfully submitted that all pending claims are now in condition for allowance. Issuance of a Notice of Allowance in due course is also respectfully requested. If a telephone conference might be of assistance, please contact the undersigned attorney at (612) 677-9050.

Respectfully Submitted,

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